# Complete Summary

## GUIDELINE TITLE

Interagency guideline on opioid dosing for chronic non-cancer pain: an educational pilot to improve care and safety with opioid treatment.

## BIBLIOGRAPHIC SOURCE(S)

Washington State Agency Medical Directors' Group. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational pilot to improve care and safety with opioid treatment. Olympia (WA): Washington State Department of Labor and Industries; 2007 Mar. 14 p. [52 references]

## GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Chronic non-cancer pain

### GUIDELINE CATEGORY

Management
Treatment

### CLINICAL SPECIALTY

Anesthesiology
Family Practice
Internal Medicine
Neurological Surgery
Neurology
Orthopedic Surgery
Pharmacology
Physical Medicine and Rehabilitation
Surgery

## INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Pharmacists
Physician Assistants
Physicians
Substance Use Disorders Treatment Providers

## GUIDELINE OBJECTIVE(S)

- To assist the primary care provider who does not specialize in pain medicine in prescribing opioids for adults in a safe and effective manner when:
    - Instituting or transitioning opioid treatment from acute to chronic non-cancer pain
    - Assessing and monitoring opioid treatment for chronic non-cancer pain
    - Weaning opioids if an opioid trial fails to yield improvements in function as well as pain
- To assist primary care providers in treating patients whose morphine equivalent dose (MED) already exceeds 120 mg per day

## TARGET POPULATION

Adults with chronic non-cancer pain who receive health care through state agency programs

**Note**: The guideline does not apply to patients with acute pain, cancer pain, and end-of-life (hospice) care.

## INTERVENTIONS AND PRACTICES CONSIDERED

1. Assessing risks and benefits of opioid treatment
2. Instituting opioid treatment including calculation of morphine equivalent dose (MED)
3. Assessing effects of treatment using tools that monitor function and pain (e.g., SF36 Health Survey, QuickDash, Quality of Life Scale, etc)
4. Monitoring adverse effects
5. Urine drug toxicology screening
6. Specialty and pain management consultation
7. Weaning opioids
8. Managing behavioral issues during weaning

9. Referrals for addiction management or opioid agonist treatment

### MAJOR OUTCOMES CONSIDERED

- Functional improvement
- Pain relief
- Safety and efficacy of opioid use
- Adverse outcomes of opioid use

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Cochrane and Medline databases were searched. Key words: opioids and hyperalgesia, opioid analgesic tolerance, opioid tolerance and respiratory depression, functional assessment, opioid detoxification

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Not Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

State health officials and actively practicing physicians who specialize in pain management developed the guidelines. The workgroup also received input from others in the medical and scientific community.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Members of various boards and commissions reviewed the guidelines and asked clarifying questions that were addressed by participating pain specialists and the interagency work group, under the guidance of the Agency Medical Directors Group.

The guideline was further refined after input from other community-based practicing physicians.

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

**Guidelines for Initiating, Transitioning, and Maintaining Oral Opioids for Chronic Non-Cancer Pain**

**Table. Summary of Recommendations**

| | |
|---|---|
| Prescribing opioid doses up to 120 mg/day morphine equivalent dose (MED):<br><br>(Cumulative daily dose when using one or more opioids. See Table 2 in the original guideline document for specific opioid thresholds.) | Before exceeding 120 mg/day MED dose threshold:<br><br>(Cumulative daily dose when using one or more opioids. See Table 2 in the original guideline document for specific opioid thresholds.) |

| | |
|---|---|
| • No pain management consultation needed if the prescriber is documenting sustained improvement in both function and pain.<br>• Consider specialty consultation* if frequent adverse effects or lack of response is evident in order to address:<br>  • Evidence of undiagnosed conditions<br>  • Presence of significant psychological condition affecting treatment<br>  • Potential alternative treatment to reduce or discontinue use of opioids | • Seek pain management consultation** to address:<br>  • Potential alternative treatment to opioids<br>  • Risk and benefit of a possible trial with opioid dose above 120 mg/day MED<br>  • Assistance with ongoing documentation of improvement in function and pain<br>  • Schedule for follow up with pain management specialist, if necessary |

*See *Specialty Consultation* section below.

**See *Pain Management Consultation* section below.

**Dosing Threshold for Pain Consultation**

In order to improve the quality of care in the state of Washington, the state agencies, in collaboration with the physician panel, reviewed the available evidence and made the following recommendations:

- In general, the total daily dose of opioid should not exceed 120 mg oral morphine equivalents.
- Rarely, and only after pain management consultation, should the total daily dose of opioid be increased above 120 mg oral morphine equivalents.
- Safety and effectiveness of opioid therapy for chronic non-cancer pain should be routinely evaluated by the prescriber.
- Assessing the effectiveness of opioid treatment should entail tracking and documenting both functional improvement and pain relief.
- A specialty consultation may be considered at any time if there is evidence of frequent adverse effects or lack of response to an opioid trial.

**Morphine Equivalent Dose Calculation**

For patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose.

All conversions between opioids are estimates generally based on "equianalgesic dosing" or ED. Patient variability in response to these EDs can be large, due primarily to genetic factors and incomplete cross-tolerance. **It is recommended that, after calculating the appropriate conversion dose, it be reduced by 25 to 50% to assure patient safety**.

See the original guideline document including Table 3 for more information. Also, refer to the "Opioid Dose Calculator" companion document (see the "Availability of Companion Documents" field).

**When to Consider Prescribing Opioids**

- Other conservative measures have failed (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], tricyclic antidepressants, antiepileptics and non-pharmacologic therapies) and opioids have not been tried.
- Patient has demonstrated sustained improvement in function and pain level in previous opioid trial.
- Patient has no relative contraindication to the use of opioids (e.g., active alcohol or other substance abuse).

**Principles for Prescribing Opioids**

- Single prescriber
- Single pharmacy
- Patient and prescriber sign opioid agreement
- Lowest possible effective dose should be used
- Be cautious when using opioids with conditions that may potentiate opioid adverse effects (including chronic obstructive pulmonary disease [COPD], congestive heart failure [CHF], sleep apnea, history of alcohol or substance abuse, elderly, or history of renal or hepatic dysfunction).
- Do not combine opioids with sedative-hypnotics, benzodiazepines or barbiturates for chronic non-cancer pain unless there is a specific medical indication for the combination.
- Assess function and pain status routinely (see *Tools for Assessing Function and Pain* section in the original guideline document).
- Monitor for medication misuse (for a list of drug-seeking behaviors, see *Reasons to Discontinue Opioids or Refer for Addiction Management* section).
- Random urine drug toxicology screening to objectively assure compliance (see *Urine Drug Toxicology Screening* section).

**Instituting Opioid Treatment for Chronic Non-Cancer Pain**

Prior to initiating chronic opioid therapy, the prescriber should comprehensively assess the risks and benefits of treatment. The prescriber is responsible for routinely monitoring the safety and effectiveness of opioid therapy in providing pain relief and improving function.

When instituting opioid therapy, both provider and patient should discuss and agree on:

- Risks and benefits of opioid therapy supported by an opioid agreement
- Treatment goals and provider's established criteria to evaluate the effectiveness of opioid therapy
- A follow-up plan with specific time intervals to monitor treatment.

Treatment goals must include improvements in both function and pain while monitoring for and minimizing adverse effects.

Depression and anxiety disorders are frequently associated with the use of opioids. Extreme caution should be used, and a specialty consultation is strongly encouraged, prior to prescribing opioids when patients have a history of significant psychological conditions such as conversion disorder, somatization, borderline personality, mood disorder, post-traumatic stress disorder (PTSD), or history of alcohol or other substance abuse.

**Transitioning Opioid Treatment from Acute Pain to Chronic Non-Cancer Pain**

- **Acute pain** is self-limiting and lasts from a few days to a few weeks following trauma or surgery.
- **Chronic pain** persists beyond the anticipated healing period for the specific disease condition.

The level of pain during an acute phase does not necessarily and accurately predict the pain level in a chronic phase. Thus, opioid dosing for chronic treatment should be assessed and adjusted accordingly.

**Tools for Assessing Function and Pain**

The key to effective opioid therapy for chronic non-cancer pain is sustained functional improvement. While there is no universally accepted tool to assess opioid treatment, it is important to use a tool that monitors both function and pain. An assessment of function should consistently measure the same elements to adequately determine the degree of progress.

See the original guideline document for the list of tools for assessing function and pain.

**Assessing Effects of Opioid Treatment**

Long-term opioid treatment is associated with the development of tolerance to its analgesic effects. Evidence is accumulating that opioid treatment may also paradoxically induce abnormal pain sensitivity, including hyperalgesia and allodynia. Thus, increasing opioid doses may not improve pain control and function.

The prescriber should assess the risks and benefits of their patient's current opioid therapy. This assessment should include:

- Function and pain status (see *Tools for Assessing Function and Pain* in the original guideline document)
- Possible adverse effects of current opioid doses
- Potential psychological condition affecting treatment
- Possible drug combinations or conditions that may potentiate opioid adverse effects (such as chronic obstructive pulmonary disease, congestive heart failure, sleep apnea, history of alcohol or substance abuse, advanced age, or history of renal or hepatic dysfunction)
- Any relative contraindication to the use of opioids (active alcohol or other substance abuse, see *Urine Drug Toxicology Screening* section).

If function and pain do not improve after a sufficient opioid trial, consider discontinuing opioids (see *Weaning Opioids* section). When there is evidence of significant adverse effects from opioid therapy, the provider should reduce the opioid dose and reassess the patient's status.

Otherwise, if no reasons for dose reduction or discontinuation are identified, and the prescriber feels (with support of objective measures of pain and function) that the patient is benefiting from current therapy, continuation would be appropriate. Ongoing therapy, however, entails ongoing assessment. The screening described above should be done on a regular basis to assess progression of therapy as the patient's condition changes over time.

**Urine Drug Toxicology Screening**

Urine drug toxicology screening can improve the prescriber's ability to safely and appropriately manage opioid treatment. Urine toxicology can verify if the patient is taking the prescribed medications. It can also identify if other psychoactive substances are consumed, but not reported, which may impact the patient's safety, function and treatment. The NIDA 5 (National Institute on Drug Abuse) is the most commonly used basic urine drug test that screens for five common drug classes:

- Cannabinoids (marijuana, hash)
- Cocaine (crack)
- Amphetamines (methamphetamines, speed)
- Opioids (heroin, opium, codeine, morphine)
- Phencyclidine (PCP)

The NIDA 5 does not screen for many other drugs of abuse, such as barbiturates, benzodiazepines, hydrocodone, methadone, oxycodone, propoxyphene, or other synthetic drugs. An expanded urine drug toxicology panel can be ordered to screen for these substances.

Positive results from a urine toxicology screen should be interpreted with caution. Over-the-counter medication may occasionally cause a positive result, particularly in the amphetamines and opioids classes. In some circumstances a positive result may require confirmatory tests and consultation with a certified Medical Review Officer (MRO). To locate a MRO in your area, submit a search at the following website: http://www.aamro.com/locate/.

**Specialty Consultation**

Specialty consultation is recommended for ongoing severe pain symptoms with no improvement in function despite treatment with opioids. Consultation should address possible undiagnosed conditions, psychological conditions affecting treatment, and alternative treatments. The type of consultation obtained should be determined by the patient's presenting signs and symptoms. Consultation may be with, but not limited to, a physician specializing in psychiatry, neurology, anesthesiology, pain, physical medicine and rehabilitation, orthopedics, addiction medicine, rheumatology, or oncology.

Chronic opioid treatment can be challenging in patients with symptoms suggestive of mood, anxiety, and psychotic disorders. Consider psychiatric and/or psychological consultation for intervention if a psychological condition is affecting treatment. Patients with signs of alcohol or other substance abuse should be referred to an addiction specialist (see *Referrals for Addiction Management or Opioid Agonist Treatment* section in the original guideline document).

**Pain Management Consultation**

Although pain may be relieved at oral morphine doses up to 120 mg per day, pain relief is not necessarily associated with psychological or functional improvement. Because sustained functional improvement is so critical to effective opioid therapy for chronic non-cancer pain, the prescriber should ensure that the patient meets the following conditions before considering a dosage above 120 mg/day morphine equivalent dose (MED):

- There are no significant psychological issues or evidence of drug-seeking behaviors, AND
- The patient has demonstrated improvement in function and pain level previously at a lower dose.

If these conditions are met, the prescriber may seek a pain management consultation for a possible trial with opioid doses above 120 mg/day MED.

Consultation with a specialist does not necessitate transfer of the patient's care or on-going opioid prescribing. However, the consultant should advise the prescribing provider on a pain management plan that may include alternative treatments to reduce or discontinue use of opioids; adequate explanation of the risks and benefits of a possible trial with opioid dosing above 120 mg/day MED; and the need for ongoing documentation of improvement in function and pain.

See the original guideline document for information on how to find a pain management specialist.

**Weaning Opioids**

Not all patients benefit from opioids, and a prescriber frequently faces the challenge of reducing the opioid dose or discontinuing the opioid altogether. From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1 mg/24 hours (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and

anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

### Recognizing and Managing Behavioral Issues during Opioid Weaning

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper.

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation ("You are indifferent to my suffering")
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary (see *Instituting Opioid Treatment for Chronic Non-Cancer Pain* section above).

## Guidelines for Optimizing Treatment When Opioid Doses Are Greater Than 120 mg MED per Day

### Assessing Effects of Opioid Doses Greater Than 120 mg MED per Day

As previously stated, ongoing opioid treatment requires ongoing assessment to optimize therapy. This is important in light of the development of hyperalgesia and other abnormal pain sensitivity with chronic high dose opioid treatment. If, after using the guidelines under *Assessing Effects of Opioid Treatment* section, the prescriber feels that current treatment is not benefiting the patient, a dose reduction or discontinuation is warranted. However, if current treatment is benefiting the patient as demonstrated by objective measures of pain and function, it may be appropriate to continue, while establishing a plan to monitor therapy as the patient's condition changes over time (see *Principles for Prescribing Opioids* section above).

### How to Discontinue Opioids or Reduce and Reassess at Lower Doses

The prescriber should assess the patient's status after discontinuing or reducing the opioid dose to less than 120 mg MED per day. If the chosen assessment tool indicates improved patient status, other than subjective pain complaints, or if there is improvement in opioid-related side effects, maintain the patient off opioids or at the new reduced dose and reassess at a later time.

Conversely, if there is evidence of functional and symptomatic deterioration following opioid taper, the prescriber can resume prior dosing or strongly consider consulting with a pain management specialist to evaluate additional therapeutic options.

**Referrals to Pain Centers**

A referral for counseling or other support during opioid taper or dose reduction is recommended if there are significant behavioral issues. In addition, a multidisciplinary pain program may be considered when appropriate to address the psychosocial and cognitive aspects of chronic pain together with patients' physical rehabilitation.

**Recognizing Aberrant Behaviors during Opioid Treatment**

Patients who exhibit aberrant behaviors may or may not be at risk for opioid abuse. There is no universally accepted screening tool to predict aberrant behaviors with opioid treatment for chronic pain. However, it is important to identify aberrant behaviors as they can affect the medical management of your patients (see *Reasons to Discontinue Opioids or Refer for Addiction Management* section below).

Patients with a co-morbid psychiatric condition or addiction are at higher risk of uncontrolled opioid use despite their attempts to follow the treatment plan. Prescribers should seek a consultation with an addiction specialist if there is co-morbid substance dependence or abuse.

**Reasons to Discontinue Opioids or Refer for Addiction Management**

- No improvement in function or pain after opioid trial
- Opioid treatment produces significant adverse effects
- Patient exhibits drug-seeking behaviors or diversion:
    - Selling prescription drugs
    - Forging prescriptions
    - Stealing or borrowing drugs
    - Frequently losing prescriptions
    - Aggressive demand for opioids
    - Injecting oral/topical opioids
    - Unsanctioned use of opioids
    - Unsanctioned dose escalation
    - Concurrent use of illicit drugs
    - Failing a drug screen
    - Getting opioids from multiple prescribers

See the original guideline document for information on referrals for addiction management or opioid agonist treatment.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate physician prescribing of opioids in a safe and effective manner, including:

- Effective opioid therapy that improves function while relieving pain
- Awareness of the risks and possible ineffectiveness of high doses
- Strategies to wean patients from unsafe doses of opioids
- Strategies to support patients through the process

### POTENTIAL HARMS

#### Adverse Effects of Opioids

- Recent studies indicate an increase in accidental deaths associated with the use of prescription opioids since 1999.
- Caution should be exercised when using opioids with conditions that may potentiate opioid adverse effects (including chronic obstructive pulmonary disease [COPD], congestive heart failure [CHF], sleep apnea, history of alcohol or substance abuse, advanced age, or history of renal or hepatic dysfunction).
- Depression and anxiety disorders are frequently associated with the use of opioids.
- Long-term opioid treatment is associated with the development of tolerance to its analgesic effects. Evidence is accumulating that opioid treatment may also paradoxically induce abnormal pain sensitivity, including hyperalgesia and allodynia.
- Opioid abstinence syndrome includes nausea, diarrhea, muscle pain and myoclonus
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.

Refer to Table 2 in the original guideline document for information on precautions for specific opioid medications.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

- Active alcohol or other substance abuse is a relative contraindication to the use of opioids.
- Opioids should not be used in conjunction with sedative-hypnotics, benzodiazepines, anti-depressants, and muscle relaxants.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

These guidelines will be introduced as an educational pilot for primary care and specialty providers who prescribe opiates for state agency clients experiencing chronic non-cancer pain. The guidelines were not developed as a disciplinary tool. After a year, the effectiveness of the new guidelines will be assessed. At that point, the state agencies may choose to implement these guidelines or a version of them in administering drug benefits through their programs.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

The year following the 2007 publication will be devoted to educating providers. Efforts to educate providers will include:

- Publication of the guideline on a new web site for the Agency Medical Directors' Group www.agencymeddirectors.wa.gov/
- Presentations at professional association meetings and conferences
- Coordinated publications by agencies participating in the Agency Medical Directors' Group
- Continuing medical education was developed for the new guidelines.

### IMPLEMENTATION TOOLS

Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness

### IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Washington State Agency Medical Directors' Group. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational pilot to improve care and safety with opioid treatment. Olympia (WA): Washington State Department of Labor and Industries; 2007 Mar. 14 p. [52 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2007 March

### GUIDELINE DEVELOPER(S)

Washington State Agency Medical Directors' Group - Independent Expert Panel

### GUIDELINE DEVELOPER COMMENT

The Washington State Agency Medical Directors Group is comprised of the medical directors and health care administrators of six state agencies: Corrections, Health, Labor & Industries, Health Care Authority, Social and Health Services, and Veterans Affairs.

### SOURCE(S) OF FUNDING

Washington State Department of Labor and Industries

### GUIDELINE COMMITTEE

Not stated

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## GUIDELINE STATUS

This is the current release of the guideline.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the Washington State Agency Medical Directors' Group Web site.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Opioid dosing guideline continuing medical education (CME) activity. Available from the Washington State Agency Medical Directors' Group Web site.
- Opioid dosing calculator. Available in Excel spreadsheet format from the Washington State Agency Medical Directors' Group Web site.
- Washington State's new guidelines for opioids for chronic non-cancer pain—frequently asked questions (March 2007). Available in Portable Document Format (PDF) from the Washington State Agency Medical Directors' Group Web site.

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI Institute on April 14, 2008. The information was verified by the guideline developer on April 24, 2008.

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